

REMARKS

Claims 1-16, 18-21, 23-24, 35-37, 39-42 and 44-45 are in the case and presented for reconsideration. Claims 1, 6, 7, 12, 13, 18, 35, and 39 are independent claims. Claims 1-5 and 7-11 have been amended. No new matter was added. Favorable reconsideration of this application in view of the foregoing remarks to follow is respectfully requested.

Informalities Objection to Claims 1-16, 18-24, 35-37 and 39-45:

Claims 1-16, 18-24, 35-37 and 39-45 stand objected due to what the Final Office Action perceives to be informalities. In particular, the Final Office Action believes that Claims 1, 6, 7, 12, 13, 18, 35 and 39 limitation “six **dimensions** of location and orientation” should read “six **degrees** of location and orientation.” In response, Applicants respectfully submit that there is absolutely no basis for the Final Office Action’s belief because the specification fully supports Claims 1-16, 18-24, 35-37 and 39-45. For example, Claim 1, as amended, recites a robot for use with a steerable catheter system comprising, *inter alia*, “**a position sensor, fixed in a vicinity of the distal tip of the catheter and adapted to generate a position signal**” and the robot includes “**a controller, adapted to receive the position signal, wherein the position signal is indicative of six dimensions of location and orientation information.**” This feature is fully described in the specification, for example one possible embodiment of the invention is described on page 27, lines 22 to 28.

The use of the above phrase “six-dimensions of location and orientation” in the base claims does not have the same meaning as “six-degrees of freedom” which is suggested in the Office Action. Applicants submit that the Examiner fails to appreciate the fact that a **degree** is a *relative* term indicating a *relative* position, intensity or amount, as of a quality or attribute The American Heritage Dictionary of the English Language: Forth Edition 2000. On the other hand,

a **dimension** is a *measure* of a spatial extent, especially width, height, or length. For example, a degree of freedom of a robotic arm refers to motion of a ridge body in three dimensional space, i.e., the ability of move forward/backward, up/down, left/right combined with rotation about three perpendicular axes.

Accordingly, as fully described in the present specification, the “[c]omputer 28 (Fig. 1), is adapted to determine the **roll** of catheter 20 in the vicinity of distal tip 34, by **using the six dimensions of information**.(emphasis added)” Page 26, lines 24-26 and page 27, lines 24 to 25. In other words, the “six dimensions of information” are a *measurement of the spatial extent*.

Accordingly, Applicants respectfully decline the Office Action’s invitation to amend the specification to define “six dimensions” as “six degrees” as the specification and Claims 1-16, 18-24, 35-37 and 39-45 are in accord with one another. Hence no correction to the claims or specification is required as suggested by the Office Action.

Applicants respectfully request withdrawal of this ground of objection.

§ 112, Second Paragraph Rejection to Claims 1-5 and 7-11:

Claims 1-5 and 7-11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, Applicants have amended independent Claims 1 and 7 by deleting the references to “apparatus” and “apparatus comprising” and have replaced the term apparatus with a “robot.” In addition, dependent Claims 2-5 and 8-11 have been amended to provide proper antecedent basis for a robot.

Accordingly, Claims 1-5 and 7-11 now particularly point out and distinctly claim a robot. No new matter was added.

Therefore, Applicants respectfully request withdrawal of this ground of rejection.

§ 103(a) Rejection to Claims 1-4, 6-10, 12, 18-24:

Claims 1-4, 6-10, 12, 18-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,808,665 issued to Green in view of U.S. Patent No. 6,123,699 issued to Webster. In response, Applicants make the following comments.

Claim 1, as amended, recites a robot for use with a steerable catheter system that includes a thumb control adapted to control a deflection of a distal tip of the catheter, comprising, *inter alia*, “a controller, adapted to receive the position signal, **the position signal being indicative of six dimensions of location and orientation information, the controller being adapted to drive the end-effector to position the distal tip of the catheter at a desired position based on the six dimensions of location and orientation information by manipulating the thumb control**.” The above feature is recited in Claim 6, 7, 12, 13, 18 and the steps of method Claims 35 and 39.

In contrast, applicants submit that the Final Office Action erroneously characterizes Green’s endoscopic surgical instrument employing a servomechanism (manipulator) (Col. 8, lines 44-57) as a robot for use with steerable catheter as recited in Claim 1. In particular, Green is directed to employing a servomechanism, which provides force and torque feedback to a manipulator (Col. 5, lines 24-28).

The Green servomechanism is not a robot. More particularly, Green fails to disclose a **controller adapted to drive an end-effector to position the distal tip of the catheter at a desired position based on the position signal which is indicative of six dimensions of location and orientation information by manipulating the thumb control** as recited in the Claims. Applicants attach herein a declaration pursuant to 37 CFR §1.132 by Assaf Govari, one of the inventors, which describes the distinction between a servomechanism and a robot.

As stated therein, a servomechanism is an automatic device employing an error-sensing feedback to an operator to allow an operator to correct the performance of a mechanism based upon a received feedback. A robot, on the other hand, is an artificial agent typically an electro-mechanical system which, by its appearance or movements, conveys a sense that it has intent or agency of its own. Thus, the Green servomechanism does not drive an end-effector based on a position signal. See, Govari declaration paragraphs 5 and 6.

Moreover, as shown in Green's FIGs. 10 and 11, a controller 140 and manipulator 142 are shown which include a wrist joint having some number of "degrees of freedom of movement" (purported to be five or six degrees in the Final Office Action on page 3). Consequently, as argued above in reference to the informalities objection to the claims, the claims do not recite six "degrees" of freedom but a position signal, which is indicative of six **dimensions** of location and orientation information. Hence, six dimensions as recited in the claims, indicates *six measures of a spatial extent*, not five or six degrees of force or torque *relative* to a hand-operated controller means as described by Green (Col. 5, lines 24-27).

With respect to Webster this reference fails to overcome the deficiencies Green. In particular, Webster discloses a deflectable electrode catheter comprising an elongated body having a deflectable tip section and a control handle where an operator can grip the control handle and slide a button by means of thumb pressure (Col. 4, lines 38-41 and Col. 8, lines 40-42). However, nowhere in Webster's disclosure is a robotic steerable catheter system disclosed comprising, *inter alia*, "**a position sensor, fixed in a vicinity of the distal tip of the catheter and adapted to generate a position signal**" and "**controller, adapted to receive the position signal, the position signal indicative of six dimensions of location and orientation information, the controller being adapted to drive the end-effector to position the distal tip of the catheter at a desired position based on the six dimensions of location and**

orientation information by manipulating the thumb control or the robot as recited in Claim 6, 7, 12, 13, 18 or the method as recited in Claims 35 and 39.

Accordingly, the hypothetical combination of Green and Webster fails to suggest or teach a robot for use with a steerable catheter as recited in Claim 1 6, 7, 12, 13, 18 or similar method as recited in Claims 35 and 39.

Therefore, Applicants respectfully request withdrawal of this ground of rejection.

§ 103(a) Rejection to Claims 5, 11, 13-16, 35-45:

Claims 5, 11, 13-16, 35-45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Green in view of Webster and U.S. Patent No. 6,246,898 issued to Vesely. In response, applicants submit that that Vesely fails to overcome the deficiencies Green and Webster.

Unlike the present invention Vesely merely discloses that a physician can draw a **path in three dimensions (3-D) space** that would be optimal to follow during a medical procedure such as brain surgery (Col. 25, lines 59-60) or followed by a catheter which can be pushed and steered using internal guide wires to the region of interest (Col. 20, lines 13-18). In other words, Vesely fails to suggest or teach a robot for use with a steerable catheter that includes a thumb control adapted to **control a deflection of a distal tip of the catheter**, *inter alia* where the distal tip of catheter is driven to a desired position based upon the **six dimensions of location and orientation** as recited by Claims 1 6, 7, 12, 13, 18, 35 and 39.

Accordingly, the hypothetical combination of Green, Webster and Vesely fails to suggest or teach a robot for use with a steerable catheter where **control a deflection of a distal tip of the catheter** is based upon **six dimensions of location and orientation** as recited in Claim 1 6, 7, 12, 13, 18 or similar method as recited in Claims 35 and 39.

§ 103(a) Rejection to Claims 1-16, 18-24, 35-37 and 39-45:

Claims 1-16, 18-24, 35-37 and 39-45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Pub. No. 2004/0254566 applied for by Plicchi et al. and U.S. Patent No. 5,417,210 issued to Funda et al. or U.S. Patent No. 5,383,852 issued to Steven-Wright. In response, Applicants make the following comments.

Applicants submit that Plicchi et al., like Green discussed above, fails to suggest or teach a robot for use with a steerable catheter where the catheter includes **a position sensor, fixed in a vicinity of the distal tip of the catheter and adapted to generate a position signal**” and the robot includes **“a controller, adapted to receive the position signal, wherein the position signal is indicative of six dimensions of location and orientation information”** and the robot is responsive to the position signal or a similar robot as recited in Claim 6, 7, 12, 13, 18 or similar method as recited in Claims 35 and 39. That is, like Green discussed above, Plicchi et al. employs a **servo-control** to steer the catheter by way of several rollers shown in FIG. 2A, reference characters 5 and 105 and described on page 3, [0027](see also Claim 1, third and fourth element). In other words, Plicchi et al. fails to teach robot responsive to a position signal. In particular, applicants submit that the Final Office Action misunderstands Plicchi et al.’s invention. Although Plicchi et al. mentions the use of a robot several times in its disclosure -- the reference to a robot is limited to describing the feeding of the catheter into the body, which is characterized as “a robotized movement system” (page 2, paragraph [0026]).

Applicants again refer the Examiner’s attention to the attached declaration pursuant to 37 CFR §1.132 by Assaf Govari, one of the inventors, which describes how Plicchi et al. discloses a servomechanism and not a robot. See Govari declaration paragraph 7.

Moreover, applicants submit that Funda et al. fails to ameliorate the deficiency of Plicchi et al. In particular, Funda et al. discloses a method of augmentation of endoscopic surgery including a hand operated distal manipulator including five degrees of freedom (Col. 4 lines 59-64 and FIG. 2). Funda et al. merely discloses a “force-sensing device” mounted on a surgical instrument (Col. 6, lines 43-46, Claim 4, preamble). In other words, Funda et al. also discloses the use of a servomechanism and not a robot.

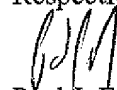
In addition, Funda et al. includes a mounted joystick or trackball to specify a desired motion of motion of a graphical object on a stereoscopic display (Col. 9, lines 65 to Col. 10 line 2). In other words, Funda et al. fails to suggest or teach a robot for use with a steerable catheter as recited in the rejected claims. Moreover, Funda et al. fails to suggest or teach a steerable catheter including a position sensor, fixed in a vicinity of the distal tip of the catheter and adapted to generate a position signal and including a controller adapted to receive the position which is **indicative of six dimensions of location and orientation** as recited in Claims 1, 6, 7, 12, 13, 18, 35 and 39.

Moreover, Applicants submit that Steven-Wright fails to overcome the deficiencies of Funda et al. In particular, Steven-Wright discloses a catheter including an elongated flexible shaft, a handle and a tip assembly, where a thumbwheel which operates pulley within the catheter (Col. 3, lines 16-22 and Col. 8, lines 52-66). In other words, Steven-Wright fails to suggest or teach a robot steerable catheter system comprising, *inter alia*, “**a position sensor, fixed in a vicinity of the distal tip of the catheter and adapted to generate a position signal**” and the robot includes “**a controller, adapted to receive the position signal, wherein the position signal is indicative of six dimensions of location and orientation information**” and the robot is responsive to the position signal or a similar robot as recited in Claim 6, 7, 12, 13, 18 or similar method as recited in Claims 35 and 39.

CONCLUSION

Early and favorable consideration of the present application, as amended herein, is respectfully requested. If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicants' undersigned attorney at the number indicated below.

Respectfully submitted,



Paul J. Esatto, Jr.

Registration No. 30,749

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 Garden City Plaza - Suite 300
Garden City, New York 11530
(516) 742-4343
PJE:DJD:tam